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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,827	04/14/2006	Ernst Kusters	33395-US-PCT	6756

1095 7590 07/16/2009

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
KLINKEL, KORTNEY L	
ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
07/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,827	KUSTERS ET AL.	
	Examiner	Art Unit	
	Kortney L. Klinkel	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9 and 10* is/are pending in the application.

4a) Of the above claim(s) *3-5,9 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

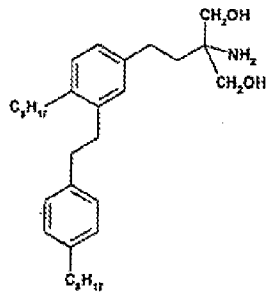
Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status

Acknowledgement is made of the remarks/amendments filed 5/18/2009. Claims 1, and 3-5 were amended. Claims 7-8 stand canceled. Claims 1-6 and 9-10 are pending in the instant Office action. Claims 3-5, and 9-10 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter. Claims 1-2 and 6 are under consideration to the extent that they read on the elected species, 2-amino-2-(2-{4-octyl-3-[2-(4-octylphenyl)-ethyl]-phenyl}-ethyl)-propane-1,3-diol that is described in Example 1 at page 4 of the specification which has the following structure:



Withdrawn Claim Rejections

Claim Rejections - 35 USC § 103

The rejection of claims 1-2 and 6 under 35 U.S.C. 103(a) as being obvious over Ehrhardt et al. (US 2007/0010494) is withdrawn in light of applicant's 103(c) exclusion statement on page 5 of the response dated 5/18/2009.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

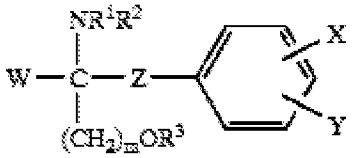
The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 and 6 are rejected under 35 U.S.C. 103(a) as being obvious over Chiba et al. (US 6004565).

Chiba teaches compounds of the following generic structure (col. 3, line 44-col 4. line 40) which are useful as immunosuppressants:



Wherein W is C1-6 alkyl substituted by 1 to 3 hydroxy groups, inter alia, m is 1-3, R1, R2 and R3 are hydrogen, alkyl or acyl, X is a straight-chain alkyl having p number of carbons, or the straight chain alkyl may have 1-3 substituents including phenyl which may have 1-3 substituents including alkyl inter alia, Y is alkyl, inter alia and Z is a straight-chin alkylene having q number of carbon atoms. p and q are the same or different and each is an integer of 1 to 20 with the proviso that p + q is between and including 6 and 23. Additionally Chiba teaches a compound, FTY720 (abstract), which has the same amino-1,3-diol head group as the elected species as well as the C8-alkyl chain off the first aryl group.

Chiba also teaches a pharmaceutical composition comprising said compounds in association with a pharmaceutically acceptable diluent or carrier (column 8, lines 19-28).

Chiba fails to teach a specific example of the elected species (the compound of example 1 at page 4) but rather teaches a structure which generically encompasses the elected compound.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to arrive at the elected species, based on the teachings of Chiba with a

reasonable expectation for success. One would have been motivated to do so because Chiba teaches a generic structure consisting of a finite number of compounds that fully encompasses the elected species which are useful as immunosuppressants, the same utility as the instant compound.

Applicant's data in the specification has been considered. The specification states at page 6 that the compounds of formula I exhibit valuable pharmacological properties such as agonism of S1P receptors as indicated by in vitro and in vivo tests. The specification then outlines various in vitro and in vivo tests and then state that compound of formula I deplete peripheral blood lymphocytes when administered at a dose of 0.03 to 3 mg/kg. There are no specific results for individual compounds. There is no indication from the specification that the compound of the elected species exhibits results that are unexpected based on the teachings of Chiba.

Response to Arguments

Applicant's arguments filed 5/16/2009 in response to the rejected claims have been fully considered, but are not persuasive.

Applicant argues that Chiba does not disclose the di-methoxy head group as required by the instantly claimed compounds. Applicant argues that Chiba teaches that W can be an alkyl group substituted by a halogen, cycloalkyl or an optionally hydroxyl substituted phenyl. Applicant argues that by this definition of W, that the head group can have a methyl group and a methoxy group. Applicant concludes that accordingly Chiba does not disclose any reason or suggestion that would motivate one or ordinary

skill in the art to modify the compounds disclosed therein to arrive a the instantly claimed compounds and therefore no rejection under 35 USC 103 can be made.

This argument is not persuasive for the following reasons. Applicant is mistaken in their interpretation of the variable W in Chiba. Column 3, lines 57-61 states wherein W is…a straight or branched chain C1-C6 alkyl substituted by 1 to 3 substituents selected from the group consisting of a halogen, a cycloalkyl, and a phenyl, which may be substituted by hydroxyl." The Examiner acknowledges that this definition of W can be read multiple ways. One way is wherein W is C1-C6 alkyl which is substituted 1 to 3 times by halogen, cycloalkyl, and phenyl; where the phenyl can be substituted by hydroxyl. A second way that this definition for W can be read is that any of the halogen, cycloalkyl and phenyl may be substituted by hydroxyl. This latter definition is the one used by the Examiner and the one Chiba likely intended. This position is supported by the fact that the working example in the disclosure of Chiba, the compound FTY720, see the structure at the top of column 5, also the abstract, has the same amino-1,3-diol head group as the elected species. This head group has to methoxy groups as required by the instantly claimed compounds. Accordingly, Chiba clearly teaches a generic set of compounds which encompass the instant elected species (the compound of example 1 at page 4). This teaching provides the reason and suggestion that would motivate one of ordinary skill in the art to arrive at the elected species. As discussed above, one would have been motivated to do so because Chiba teaches a generic structure consisting of a finite number of compounds that fully encompasses the elected species which are useful as immunosuppressants, the same utility as the instant compound.

Applicant has not provided evidence of unexpected results for the elected species or any of the claimed compounds over the teachings of Chiba. As such, the claims are deemed properly rejected under 35 USC 103.

Conclusion

Claims 1-2 and 6 are rejected. No claim is allowed.

No new ground(s) of rejection were presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kortney Klinkel, whose telephone number is (571)270-5239. The examiner can normally be reached on Monday-Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KLK

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611